# UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF ILLINOIS EASTERN DIVISION

GRISSELLE RAMOS, on behalf of herself and ) all others similarly situated,	Civil Action No. 08-CV-2703
Plaintiff, )	
v. )	Judge Joan Humphrey Lefkow
PLAYTEX PRODUCTS, INC., RC2 (CORPORATION, LEARNING CURVE (CORPORATION)	Magistrate Judge Schenkier
BRANDS, INC., and MEDELA, INC.,  Defendants.	JURY TRIAL DEMANDED
JESSICA SMITH, on behalf of herself and all others similarly situated,	Civil Action No. 08-CV-3352
Plaintiff, ) v.	
PLAYTEX PRODUCTS, INC., RC2 (CORPORATION, LEARNING CURVE (CORPORATION)	Judge Joan Humphrey Lefkow
BRANDS, INC., and MEDELA, INC.,  Defendants.	JURY TRIAL DEMANDED

# DEFENDANT MEDELA INC.'S ANSWER AND DEFENSES TO PLAINTIFF JESSICA SMITH'S CLASS ACTION COMPLAINT

Defendant Medela Inc. ("Medela") by and through its attorneys, Winston & Strawn LLP, states, for its answer and defenses to the Class Action Complaint ("Complaint") of Plaintiff Jessica Smith ("Plaintiff"), as follows:

# PRELIMINARY STATEMENT

On or about January 31, 2008, California's Center for Environmental Health ("CEH") identified the cooler carriers in two Medela products in a Notice of Violation and

alleged lead exposure violations under California's Proposition 65. Plaintiff identifies these CEH's "findings" as the basis for the claims in her Complaint.

Medela's cooler carriers, referred to herein as "bottle cooler carriers," are not used to feed children. Rather, they are used to store bottles. Breastmilk is stored in the bottles, and the bottles are used to feed children. An independent laboratory tested the bottle cooler carriers identified by CEH and found no risk of lead exposure or lead ingestion for children related to the bottle cooler carriers. Testing also showed that there is no detectable lead in the bottles or any components in the path of the breastmilk. Based on these test results, CEH affirmatively decided not to pursue any of the allegations in its Notice of Violation.

It is widely known that lead is hazardous only when an individual is actually exposed to lead, and exposed to sufficiently high levels of lead. Without exposure to lead (at sufficiently high levels) resulting from use of a product, there can be no lead-related injury caused by that product. Here, because no individual was exposed to lead at any level based on reasonable use of the bottle cooler carrier, there can be no injury related to reasonable use of the bottle cooler carrier.

Many paragraphs in the Complaint refer to multiple defendants; Defendant Medela answers only for itself. To the extent and degree that the paragraphs in the Complaint contain allegations about other defendants, no response is required by Medela. To the extent and degree a response to such allegations is required, Medela lacks knowledge or information sufficient to form a belief as to the truth of the allegations pertaining to the other defendants. Medela further states that it has no involvement in, input on, or control over the business decisions and activities of the other defendants.

### I. OVERVIEW

1. Plaintiffs bring this action as a Class Action pursuant to Rules 23(a), (b)(1), (b)(2) and (b)(3) of the Federal Rules of Civil Procedure on behalf of all persons who purchased vinyl plastic baby products ("VPBPs") which contain lead and which were imported and/or distributed by Defendants. The VPBPs at issue include: a vinyl cooler for storing breast milk made by Medela; a carrying case for a First Years "Natural Transitions" breast pump made by RC2; and a Playtex "Fridge to Go" vinyl baby bottle cooler.

ANSWER: This Paragraph contains allegations directed to and pertaining to defendants other than Medela, and as to those allegations no response is required from Medela. To the extent a response to those allegations is required, Medela states that it lacks knowledge or information sufficient to form a belief as to the truth of the allegations pertaining to the other defendants. Medela admits that Plaintiff styled the complaint as a class action and that the complaint included allegations about Medela. Medela denies all other allegations contained in Paragraph 1 of the Complaint. Further, Medela denies any allegation or implication that lead content of a product equates to actual exposure to lead, much less exposure to lead in concentrations that could be injurious.

2. Despite marketing their VPBPs as safe for young children, Defendants distributed VPBPs that are intended to hold milk to be ingested by newborns but that contain lead which is poisonous to children, especially if ingested.

ANSWER: This Paragraph contains allegations directed to and pertaining to defendants other than Medela, and as to those allegations no response is required from Medela. To the extent a response to those allegations is required, Medela states that it lacks knowledge or information sufficient to form a belief as to the truth of the allegations pertaining to the other defendants. Medela admits that it has marketed its products, including a bottle cooler carrier for storing bottles that store breast milk. Medela states that its bottle cooler carrier is not used to feed children; rather it is used to store bottles. Breastmilk is stored in the bottles, and the bottles are used to feed children. Medela states that the specific content of its marketing for its products

has varied over time. Because the allegations in Paragraph 2 of the Complaint do not identify or specify any particular marketing campaign or piece, it is impossible for Medela to provide a more specific answer regarding its marketing. To the extent a further response is required to allegations pertaining to Medela's marketing, Medela lacks knowledge or information sufficient to form a belief as to the truth of such allegations. Medela denies the remaining allegations contained in Paragraph 2 of the Complaint. Further, Medela denies any allegation or implication that lead content of a product equates to actual exposure to lead, much less exposure to lead in concentrations that could be injurious.

3. Defendants did so despite clear regulatory prohibitions on the use of lead in other children's products, their knowledge that the ingestion of lead by children can cause serious long-term injury, their prior experiences with the marketing and sale of children's toys tainted with lead paint, and their representations that the VPBPs are safe for children.

ANSWER: This Paragraph contains allegations directed to and pertaining to defendants other than Medela, and as to those allegations no response is required from Medela. To the extent a response to those allegations is required, Medela states that it lacks knowledge or information sufficient to form a belief as to the truth of the allegations pertaining to the other defendants. Medela denies the remaining allegations contained in Paragraph 3 of the Complaint. Further, Medela denies any allegation or implication that lead content of a product equates to actual exposure to lead, much less exposure to lead in concentrations that could be injurious. Medela further states that lead is hazardous only when an individual is actually exposed to lead, and exposed to sufficiently high levels of lead, and further that no individual was exposed to lead at any level based on reasonable use of Medela's bottle cooler carrier.

4. High levels of lead were found in Defendants' VPBPs by an environmental group based in California, the Center for Environmental Health ("CEH"). CEH is recommending that parents discard the vinyl coolers and vinyl cases used for storing milk, or other infant products.

ANSWER: This Paragraph contains allegations directed to and pertaining to defendants other than Medela, and as to those allegations no response is required from Medela. To the extent a response to those allegations is required, Medela states that it lacks knowledge or information sufficient to form a belief as to the truth of the allegations pertaining to the other defendants. Medela lacks knowledge or information sufficient to form a belief as to the truth of the allegation that CEH is recommending that parents discard Medela's bottle cooler carrier or Medela's other products. Medela states, however, that CEH affirmatively decided not to pursue any of its allegations against Medela. Medela denies the remaining allegations contained in Paragraph 4 of the Complaint. Further, Medela denies any allegation or implication that lead content of a product equates to actual exposure to lead, much less exposure to lead in concentrations that could be injurious.

5. Despite the CEH report, Defendants have not offered to reimburse Plaintiffs and the Class for the costs of the VPBPs. At one time, one Defendant (Medela) offered to replace the product, but only at some undetermined date in the future. Defendants are thus failing to compensate Plaintiffs and the Class for their damages or make them whole.

ANSWER: This Paragraph contains allegations directed to and pertaining to defendants other than Medela, and as to those allegations no response is required from Medela. To the extent a response to those allegations is required, Medela states that it lacks knowledge or information sufficient to form a belief as to the truth of the allegations pertaining to the other defendants. Medela admits that it has made various offers, at different times, to replace its bottle cooler carrier or refund the cost of the bottle cooler carrier. Medela states that the terms of those offers varied. To the extent that the allegations contained in Paragraph 5 state a legal conclusion,

no response is required; to the extent a response to such allegations is required, Medela denies such allegations. Medela denies the remaining allegations contained in Paragraph 5 of the Complaint.

6. As a result of Defendants' negligent and reckless conduct, Plaintiffs' children and the children of the Class have been significantly exposed to a known hazardous substance. As a result of such exposure, the children are at an increased risk of being poisoned by lead. Early detection, through medical testing, of lead poisoning is made necessary and advisable by the Defendants' manufacturing, marketing, and sale of the VPBPs tainted with lead.

ANSWER: This Paragraph contains allegations directed to and pertaining to defendants other than Medela, and as to those allegations no response is required from Medela. To the extent a response to those allegations is required, Medela states that it lacks knowledge or information sufficient to form a belief as to the truth of the allegations pertaining to the other defendants. As to the allegations directed to and pertaining to Medela, Medela denies the allegations contained in Paragraph 6 of the Complaint. Further, Medela denies any allegation or implication that lead content of a product equates to actual exposure to lead, much less exposure to lead in concentrations that could be injurious. Medela further states that lead is hazardous only when an individual is actually exposed to lead, and exposed to sufficiently high levels of lead, and further that no individual was exposed to lead at any level based on reasonable use of Medela's bottle cooler carrier.

7. Accordingly, Plaintiffs bring this action to recover the actual and compensatory damages for themselves and the Class, as well as to recover the costs of diagnostic testing necessary to detect lead poisoning to their children resulting from Defendants' actions.

ANSWER: This Paragraph contains allegations directed to and pertaining to defendants other than Medela, and as to those allegations no response is required from Medela. To the extent a response to those allegations is required, Medela states that it lacks knowledge or

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information sufficient to form a belief as to the truth of the allegations pertaining to the other defendants. Medela admits that Plaintiff has brought a suit styled as a class action. Medela states that the Complaint speaks for itself. Medela denies the remaining allegations in Paragraph 7 of the Complaint. Further, Medela denies any allegation or implication that lead content of a product equates to actual exposure to lead, much less exposure to lead in concentrations that could be injurious. Medela further states that lead is hazardous only when an individual is actually exposed to lead, and exposed to sufficiently high levels of lead, and further that no individual was exposed to lead at any level based on reasonable use of Medela's bottle cooler carrier.

#### II. PARTIES

8. Plaintiff Jessica Smith ("Plaintiff') is a citizen of the State of California, residing at 919 Levering Avenue, Los Angeles, California 90024. Plaintiff purchased one or more VPBPs based on Defendants' representations that the products are safe for children and are intended to be used in connection with feeding infants. Plaintiff was deceived because Defendants could not have represented the VPBPs were safe had they truthfully disclosed that the products were made with lead. Plaintiff would never have purchased these VPBPs had she known her infant would be exposed to lead.

ANSWER: This Paragraph contains allegations directed to and pertaining to defendants other than Medela, and as to those allegations no response is required from Medela. To the extent a response to those allegations is required, Medela states that it lacks knowledge or information sufficient to form a belief as to the truth of the allegations pertaining to the other defendants. Medela lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Plaintiff's citizenship and residence. Medela lacks knowledge or information sufficient to form a belief as to the truth of the allegation that Plaintiff may have purchased Medela's product. If Plaintiff purchased Medela's product, Medela lacks knowledge or information sufficient to form a belief as to the truth of the allegations about Plaintiff's

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motivation(s) and reason(s) for purchasing Medela's product. Medela denies the remaining allegations in Paragraph 8 of the Complaint. Further, Medela denies any allegation or implication that lead content of a product equates to actual exposure to lead, much less exposure to lead in concentrations that could be injurious. Medela further states that lead is hazardous only when an individual is actually exposed to lead, and exposed to sufficiently high levels of lead, and further that no individual was exposed to lead at any level based on reasonable use of Medela's bottle cooler carrier.

Playtex, Inc. is a Delaware corporation with its principal place of business at 300 Nyala Farms Road, Westport, Connecticut 06880.

**ANSWER:** The allegations contained in Paragraph 9 of the Complaint make no averments with respect to Medela and, therefore, no response is required by it. To the extent a response is required, Medela lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 9 of the Complaint.

RC2 Corporation is a Delaware corporation with its principal place of business located at 111 W. 22nd Street, Suite 320, Oak Brook, Illinois 60523.

The allegations contained in Paragraph 10 of the Complaint make no **ANSWER:** averments with respect to Medela and, therefore, no response is required by it. To the extent a response is required, Medela lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 10 of the Complaint.

11. Learning Curve Brands, Inc. is incorporated in Delaware, with its headquarters in Oak Brook, Illinois, and is a subsidiary of RC2. Learning Curve markets and sells what it purports to be "developmental toys that engage children, and provide parents with peace of mind, knowing their children are being inspired and enlightened by safe and quality playthings." Learning Curve brands include The First Years®, Lamaze®, John Deere KidsTM, Thomas & FriendsTM and Bob the Builder, among others. Learning Curve is responsible for the licensing, marketing, and distribution of the toys, collectibles, and infant and toddler and preschool

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products manufactured by RC2 Corporation. These products include the VPBPs at issue. In 2003, shortly after its acquisition by RC2 Corporation, Learning Curve Brands issued a recall of 3,800 activity toys due to unsafe levels of lead in the paint. Moreover, in 2007, Learning Curve issued two recalls for 1.5 million Thomas & Friends toys painted with red and yellow surface paint containing lead. Learning Curve was formerly known as The Ertl Company, Racing Champions, Ertl, Inc., RC Ertl, Inc. and RC2 Brands, Inc.

The allegations contained in Paragraph 11 of the Complaint make no **ANSWER:** averments with respect to Medela and, therefore, no response is required by it. To the extent a response is required, Medela lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 11 of the Complaint.

Medela Inc. is a Delaware corporation with its principal place of business located 12. at 1101 Corporate Drive, McHenry, Illinois 60050.

Medela admits that it is registered in Delaware and maintains its place of **ANSWER:** business at 1101 Corporate Drive in McHenry, Illinois, 60050.

#### III. JURISDICTION AND VENUE

This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(d), because at least one member of the class is a citizen of a different State than the Defendants, there are 100 or more class members, and the aggregate amount in controversy exceeds \$5,000,000, exclusive of interest and cost.

The allegations contained in Paragraph 13 of the Complaint state legal **ANSWER:** conclusions to which no response is required. To the extent a response is required, Medela admits that this Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(d) and § 1453.

14. Venue is properly set in this District pursuant to 28 U.S.C. § 1391(a) because one or more Defendants reside, transact business, and are found within this District, and a substantial part of the events giving rise to the claims at issue in this Complaint arose in this District.

ANSWER: The allegations contained in Paragraph 14 of the Complaint state legal conclusions to which no response is required. To the extent a response is required, Medela admits that venue is proper in this District.

### IV. FACTUAL ALLEGATIONS

#### A. VPBPs

15. Vinyl (the common name for the polymer polyvinyl chloride) is a versatile and durable material used in a variety of household products, including toys, children's accessories, and Defendants' VPBPs.

**ANSWER:** Medela lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 15 of the Complaint.

16. Vinyl, to hold together, needs a metal as a binding agent. In the U.S., the metal of choice often is tin, calcium, barium or zinc. In fact, according to the Vinyl Institute, a trade group based in Arlington, Va., the vinyl industry in the United States stopped using lead in plastic years ago and instead uses tin, calcium, barium or zinc as a stabilizer to provide durability.

**ANSWER:** Medela lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 16 of the Complaint.

17. But lead or cadmium—far more reactive and harmful—are cheaper. Thus, imported vinyl products from China and other overseas locations still contain lead.

ANSWER: The allegations in Paragraph 17 of the Complaint are vague and ambiguous as stated, and, therefore, Medela lacks knowledge or information sufficient to form a belief as to the truth of the allegations and demands strict proof thereof.

## B. Overview of Lead Poisoning

### 1. Effects of lead on children

18. Lead in VPBPs is invisible to the naked eye and has no smell. Yet, lead is known to be very dangerous to human beings. Essentially, lead lodges in the bone or skeletal structure of the body and certain events can cause it to latently move into the blood stream and cause significant difficulties.

ANSWER: The allegations in Paragraph 18 of the Complaint are vague and ambiguous as stated, and, therefore, Medela lacks knowledge or information sufficient to form a belief as to the truth of the allegations and demands strict proof thereof.

19. The U.S. Center for Disease Control has set a blood lead "level of concern" of a mere 10 micrograms per deciliter of blood (a microgram is 1/1,000,000th of a gram and a deciliter is 1/10th of a liter or about 1/10 of a quart), and new research suggests that serious health effects may begin to set in with blood levels as low as 5 micrograms per deciliter.

ANSWER: The allegations in Paragraph 19 of the Complaint are vague and ambiguous as stated, and, therefore, Medela lacks knowledge or information sufficient to form a belief as to the truth of the allegations and demands strict proof thereof.

20. On average, children under six will absorb and/or retain about 50 percent of the lead they ingest. Lead poisoning during the first three years of a child's life can critically impair brain and nervous system development. Young children are the most vulnerable to poisoning by lead, due in large part to the fact that their brains and nervous systems have yet to fully form. The direct effects of pediatric lead poisoning can include reading disabilities, attention deficit, hyperactivity, behavioral problems, stunted growth, hearing impairment and damage to the kidneys and greater demand for medical care generally to treat those problems. If exposed to higher levels, young children may suffer from mental retardation, fall into a coma, or die.

ANSWER: The allegations in Paragraph 20 of the Complaint are vague and ambiguous as stated, and, therefore, Medela lacks knowledge or information sufficient to form a belief as to the truth of the allegations and demands strict proof thereof.

21. Health officials figure lead use in gasoline and paints skimmed five to 10 IQ points from every child growing up in the United States in the 1970s. New research suggests that

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the so-called "natural" decline in mental capacity afflicting many older people is instead a function of lead exposure decades earlier, as children and young adults.

The allegations in Paragraph 21 of the Complaint are vague and **ANSWER:** ambiguous as stated, and, therefore, Medela lacks knowledge or information sufficient to form a belief as to the truth of the allegations and demands strict proof thereof.

The American Academy of Pediatrics has thus concluded that there is "no known 22. safe level of lead exposure."

**ANSWER:** The allegations in Paragraph 22 of the Complaint are vague and ambiguous as stated, and, therefore, Medela lacks knowledge or information sufficient to form a belief as to the truth of the allegations and demands strict proof thereof.

23. Because the body absorbs lead over time, even small amounts of lead can have negative effects. There is no study that has established a blood level for lead that does not impair child cognition.

The allegations in Paragraph 23 of the Complaint are vague and **ANSWER:** ambiguous as stated, and, therefore, Medela lacks knowledge or information sufficient to form a belief as to the truth of the allegations and demands strict proof thereof.

24. Children can be exposed to lead through such things as contaminated dust, paint chips, or lead-based products. Children may be exposed to lead from consumer products through normal hand-to-mouth activity, which is part of their development. Children often place toys, fingers, and other objects in their mouth, exposing themselves to lead dust.

Medela admits that children can be exposed to lead from various sources **ANSWER:** and a variety of mechanisms. Medela denies any allegation or implication that children have been or could be exposed to lead from or through its vinyl cooler. Medela lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 24 of the Complaint. Further, Medela denies any allegation or implication that lead content of a product equates to actual exposure to lead, much less exposure to lead in concentrations that could be injurious. Medela further states that lead is hazardous only when an individual is actually exposed to lead, and exposed to sufficiently high levels of lead, and further that no individual was exposed to lead at any level based on reasonable use of Medela's bottle cooler carrier.

According to the National Safety Council, it only takes the lead dust equivalent of a single grain of salt for a child to register an elevated blood lead level.

The allegations in Paragraph 25 of the Complaint are vague and **ANSWER:** ambiguous as stated, and, therefore, Medela lacks knowledge or information sufficient to form a belief as to the truth of the allegations and demands strict proof thereof.

26. A universally recognized method for testing lead levels is a blood test. The reliability of blood lead testing comes from, in part, the capability of comparing blood lead test results, especially for children, to the published standard of 10 µg/dl, established by the Center for Disease Control ("CDC").

**ANSWER:** The allegations in Paragraph 26 of the Complaint are vague and ambiguous as stated, and, therefore, Medela lacks knowledge or information sufficient to form a belief as to the truth of the allegations and demands strict proof thereof.

27. Blood lead testing is also useful in signaling a need for further medical examinations, which can lead to a more definite diagnosis.

The allegations in Paragraph 27 of the Complaint are vague and **ANSWER:** ambiguous as stated, and, therefore, Medela lacks knowledge or information sufficient to form a belief as to the truth of the allegations and demands strict proof thereof.

# 2. Effects of Lead Poisoning on Society

28. While it is clear that lead poisoning has a drastic effect on the children and families who suffer from its devastating physiological and neurological effects, there are public costs as well.

ANSWER: The allegations in Paragraph 28 of the Complaint are vague and ambiguous as stated, and, therefore, Medela lacks knowledge or information sufficient to form a belief as to the truth of the allegations and demands strict proof thereof.

29. The annual costs of environmentally attributable diseases in American children total \$54.9 billion, of which the vast majority arises from lead poisoning. It is estimated that the total cost of lead poisoning in the U.S. each year is \$43.4 billion. *See* Landrigan, Philip J. et al., "Environmental Pollutants and Disease in American Children: Estimates of Morbidity, Mortality, and Costs for Lead Poisoning, Asthma, Cancer, and Developmental Disabilities," Environmental Health Perspectives (Vol. 110, No. 7, July 2002).

ANSWER: The allegations in Paragraph 29 of the Complaint are vague and ambiguous as stated, and, therefore, Medela lacks knowledge or information sufficient to form a belief as to the truth of the allegations and demands strict proof thereof. Medela further states that the article cited in Paragraph 29 of the Complaint speaks for itself.

# C. Lead in Defendants' VPBPs

30. High levels of lead were found in defendants' VPBPs by an environmental group based in California, the Center for Environmental Health ("CEH"), that spread the word about lead in vinyl baby bibs, lunchboxes, and other children's products.

ANSWER: This Paragraph contains allegations directed to and pertaining to defendants other than Medela, and as to those allegations no response is required from Medela. To the extent a response to those allegations is required, Medela states that it lacks knowledge or information sufficient to form a belief as to the truth of the allegations pertaining to the other defendants. Medela denies the remaining allegations in Paragraph 30 of the Complaint. Further, Medela denies any allegation or implication that lead content of a product equates to

actual exposure to lead, much less exposure to lead in concentrations that could be injurious. Medela further states that lead is hazardous only when an individual is actually exposed to lead, and exposed to sufficiently high levels of lead, and further that no individual was exposed to lead at any level based on reasonable use of Medela's bottle cooler carrier.

CEH purchased VPBPs in January 2008 from Target and Babies "R" Us stores in 31. the San Francisco Area. CEH found a vinyl cooler for stored breast milk with high levels of lead from a "Pump in Style" breast pump made by Medela; also with high lead levels was a carrying case that came with a First Years "Natural Transitions" breast pump made by RC2 Brands, Inc., makers of Thomas and Friends products; and a Playtex "Fridge to Go" vinyl baby bottle cooler.

**ANSWER:** This Paragraph contains allegations directed to and pertaining to defendants other than Medela, and as to those allegations no response is required from Medela. To the extent a response to those allegations is required, Medela states that it lacks knowledge or information sufficient to form a belief as to the truth of the allegations pertaining to the other defendants. Medela lacks knowledge or information sufficient to form a belief as to the truth of the allegation that CEH purchased a Medela bottle cooler carrier in January 2008 from Target and/or Babies "R" Us stores in the San Francisco Area. Medela denies the remaining allegations in Paragraph 31 of the Complaint. Further, Medela denies any allegation or implication that lead content of a product equates to actual exposure to lead, much less exposure to lead in concentrations that could be injurious. Medela further states that lead is hazardous only when an individual is actually exposed to lead, and exposed to sufficiently high levels of lead, and further that no individual was exposed to lead at any level based on reasonable use of Medela's bottle cooler carrier

32. CEH tested each of the VPBPs first with a hand-held metal detector and then at a laboratory. The products were found to have from 1,100 parts per million of lead to 5,500 parts per million of lead, the group says. CEH has informed the producers of the products. "Parents would never expect that when storing breast milk for their newborn, it could be contaminated by

lead," said Michael Green, Executive Director of CEH. "There is no reason to have lead in baby products or anything used to hold breast milk for infants."

**ANSWER:** This Paragraph contains allegations directed to and pertaining to defendants other than Medela, and as to those allegations no response is required from Medela. To the extent a response to those allegations is required, Medela states that it lacks knowledge or information sufficient to form a belief as to the truth of the allegations pertaining to the other defendants. Medela admits that CEH has purported to test a bottle cooler carrier manufactured by Medela; that CEH purported to have obtained results from that test that show lead content for Medela's bottle cooler carrier; and that CEH informed Medela of that information. Medela denies that its bottle cooler carrier has high lead content, denies the allegation or implication that lead content of a product equates to actual exposure to lead; denies that any breast milk was contaminated by lead as a result of the use of Medela's bottle cooler carrier; and denies that anyone has been exposed to lead from its bottle cooler carrier. Medela further states that CEH affirmatively decided not to pursue any of its allegations against Medela. Medela lacks knowledge or information sufficient to form a belief as to whether the Executive Director of CEH asserted the opinions that are attributed to him in Paragraph 32, or as to the truth of such opinions. Medela denies the remaining allegations in Paragraph 32 of the Complaint.

33. CEH is recommending that parents discard the vinyl coolers and vinyl cases used for storing breast milk, pacifiers, or other infant products.

ANSWER: This Paragraph contains allegations directed to and pertaining to defendants other than Medela, and as to those allegations no response is required from Medela. To the extent a response to those allegations is required, Medela states that it lacks knowledge or information sufficient to form a belief as to the truth of the allegations pertaining to the other defendants. Medela lacks knowledge or information sufficient to form a belief as to the truth of

the remaining allegations in Paragraph 33 of the Complaint. Further, Medela denies any allegation or implication that lead content of a product equates to actual exposure to lead, much less exposure to lead in concentrations that could be injurious. Medela further states that lead is hazardous only when an individual is actually exposed to lead, and exposed to sufficiently high levels of lead, and further that no individual was exposed to lead at any level based on reasonable use of Medela's bottle cooler carrier. Medela further states that CEH affirmatively decided not to pursue any of its allegations against Medela.

34. Despite the obvious and serious dangers of lead contamination of infants, none of the Defendants has instituted a recall of the products.

ANSWER: This Paragraph contains allegations directed to and pertaining to defendants other than Medela, and as to those allegations no response is required from Medela. To the extent a response to those allegations is required, Medela states that it lacks knowledge or information sufficient to form a belief as to the truth of the allegations pertaining to the other defendants. Medela admits that it has not issued a recall for its bottle cooler carrier. Medela denies the allegation or implication that Medela's bottle cooler carrier exposed consumers, children, or infants to lead, and, therefore, denies that a recall was warranted or should have been undertaken. Medela denies the remaining allegations in Paragraph 34 of the Complaint.

# D. Defendants' Knowledge of the Danger of Lead in Children's Products

35. The Consumer Product Safety Commission ("CPSC") is supposed to take steps to prevent children from being exposed to hazardous lead and cadmium (and any other substance) in consumer products under the Consumer Product Safety Act ("CPSA"), 15 U.S.C. §§ 2051-84, and the Federal Hazardous Substances Act ("FHSA"), 15 U.S.C. §§ 1261-78.

**ANSWER:** The allegations contained in Paragraph 35 of the Complaint state legal conclusions to which no response is required. To the extent a response is required, Medela states

that the Consumer Product Safety Act and the Federal Hazardous Substances Act speak for themselves, and that Medela lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 35 of the Complaint.

36. In 1978, the CPSC banned paint containing in excess of 0.06% lead by weight intended for consumer use. At the same time, it also banned toys and other articles intended for use by children that use paint with a lead content in excess of 0.06% because they present a risk of lead poisoning to young children. *See* 16 C.F.R. Part 1303.

ANSWER: The allegations contained in Paragraph 36 of the Complaint state legal conclusions to which no response is required. To the extent a response is required, Medela states that the regulation speaks for itself and that Medela lacks knowledge or information sufficient to form a belief as to the truth of the allegations. Medela denies that the bottle cooler carrier is a toy or other article intended for use by children and denies that it uses paint. Further, Medela denies any allegation or implication that lead content of a product equates to actual exposure to lead, much less exposure to lead in concentrations that could be injurious. Medela further states that lead is hazardous only when an individual is actually exposed to lead, and exposed to sufficiently high levels of lead, and further that no individual was exposed to any lead based on reasonable use of Medela's bottle cooler carrier.

37. Both the United States House and Senate have passed versions of an amendment to the CPSA that would put a limit on the total amount of lead that could be in children's products, no matter the materials. The Senate amendment passed by a vote of 79-13, while the House amendment passed unanimously. Both the Senate and House versions would ultimately forbid the sale of products with levels of lead higher than 100 parts per million, levels which are exceeded by the Defendants' VPBPs *by 11 to 55 times*. *See* H.R. 4040; S. 2663.

ANSWER: This Paragraph contains allegations directed to and pertaining to defendants other than Medela, and as to those allegations no response is required from Medela. To the extent a response to those allegations is required, Medela states that it lacks knowledge or

information sufficient to form a belief as to the truth of the allegations pertaining to the other defendants. To the extent that the allegations contained in Paragraph 37 state legal conclusions, no response is required. To the extent a response to such allegations is required, Medela admits that bills are pending in both the United State House and Senate that would put a limit on total lead content in certain children's products of 300 parts per million at the outset, possibly reduced to 100 parts per million over time. Medela lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 37 of the Complaint relating to purported margins of vote. Medela denies the remaining allegations in Paragraph 37. Further, Medela denies any allegation or implication that lead content of a product equates to actual exposure to lead, much less exposure to lead in concentrations that could be injurious. Medela further states that lead is hazardous only when an individual is actually exposed to lead, and exposed to sufficiently high levels of lead, and further that no individual was exposed to any lead based on reasonable use of Medela's bottle cooler carrier.

38. Since 1973, Illinois has prohibited the sale of any children's products containing lead at a level of 600 parts per million. See 410 ILCS 45 (Lead Poisoning Prevention Act). Legislation is currently under consideration in the Illinois General Assembly which would lower the permissible level to 40 parts per million. See Ill. H.B. 5705, 5789, S.B. 2868.

The allegations contained in Paragraph 38 of the Complaint state legal **ANSWER:** conclusions to which no response is required. To the extent a response is required, Medela states that the statute and proposed laws speak for themselves. Further, Medela denies that Illinois has prohibited the sale of any children's products containing lead at a level of 600 parts per million since 1973. Medela admits that effective June 20, 2006, the Illinois Lead Poisoning Prevention Act was amended to prohibit, *inter alia*, the sale of "articles used by or intended to be chewable by children" containing lead at a level more than 600 parts per million, and that legislation (called the Child-Safe Chemicals Act) is currently under consideration in the Illinois House and Senate which would, *inter alia*, regulate the sale of certain children's products and product components containing lead at a level more that 40 parts per million effective July 1, 2009. Medela denies the remaining allegations contained in paragraph 38 of the Complaint.

39. Twenty-three other states have already enacted or are considering legislation setting permissible levels of lead well below the levels found in the vinyl coolers and cases. For example, legislation enacted in Washington state sets the permissible level of lead in children's products to a maximum of 90 parts per million, and possibly as low as 40 parts per million, *see* Wash. H.B. 2647, and similar legislation is under consideration in California, *see* Cal. A.B. 2694 (setting permissible level of lead at 40 parts per million).

ANSWER: This Paragraph contains allegations directed to and pertaining to defendants other than Medela, and as to those allegations no response is required from Medela. To the extent a response to those allegations is required, Medela states that it lacks knowledge or information sufficient to form a belief as to the truth of the allegations pertaining to the other defendants. As regarding Medela, Medela states that the laws of the various jurisdictions speak for themselves. Further, Medela states that the allegations in Paragraph 39 are vague and ambiguous as stated, and, therefore, Medela lacks knowledge or information sufficient to form a belief as to the truth of the allegations and demands strict proof thereof. Further, Medela denies any allegation or implication that lead content of a product equates to actual exposure to lead, much less exposure to lead in concentrations that could be injurious. Medela further states that lead is hazardous only when an individual is actually exposed to lead, and exposed to sufficiently high levels of lead, and further that no individual was exposed to lead at any level based on reasonable use of Medela's bottle cooler carrier.

40. Thus, since at least 1973, Defendants have been on notice of the dangers of lead in children's products. Yet despite this knowledge, they continue to market products as "safe" when in fact they are not safe and contain lead.

ANSWER: This Paragraph contains allegations directed to and pertaining to defendants other than Medela, and as to those allegations no response is required from Medela. To the extent a response to those allegations is required, Medela states that it lacks knowledge or information sufficient to form a belief as to the truth of the allegations pertaining to the other defendants. Medela denies the allegations contained in Paragraph 40 of the Complaint. Further, Medela denies any allegation or implication that lead content of a product equates to actual exposure to lead, much less exposure to lead in concentrations that could be injurious. Medela further states that lead is hazardous only when an individual is actually exposed to lead, and exposed to sufficiently high levels of lead, and further that no individual was exposed to lead at any level based on reasonable use of Medela's bottle cooler carrier.

## E. Defendants' Marketing of VPBPs

41. Defendants' marketing campaigns are built around assuring parents that their products are safe for children.

ANSWER: This Paragraph contains allegations directed to and pertaining to defendants other than Medela, and as to those allegations no response is required from Medela. To the extent a response to those allegations is required, Medela states that it lacks knowledge or information sufficient to form a belief as to the truth of the allegations pertaining to the other defendants. Medela admits that it has marketed its products, including a bottle cooler carrier for storing breast milk. Medela states that the specific content of its marketing for its products has varied over time. Because the allegations in Paragraph 41 of the Complaint do not identify or specify any particular marketing campaign or piece, it is impossible for Medela to provide a more specific answer regarding its marketing. To the extent a further response is required to

allegations pertaining to Medela's marketing, Medela lacks knowledge or information sufficient to form a belief as to the truth of such allegations.

- 42. For example, on their website, RC2 and Learning Curve state:
  - a. "We understand that what matters most to parents is keeping their children healthy, happy and safe. What matters most to us is helping parents do just that by offering products for every stage of your child's development . . . ."
  - b. "Learning Curve offers developmental toys that engage children, and provide parents with peace of mind, knowing their children are being inspired and enlightened by *safe and quality playthings*." (emphasis supplied).
  - c. "From breast pumps to pacifiers and sippy cups, The First Years by Learning Curve provides *high-value* feeding items to nurture your child." (emphasis supplied).
  - d. "Nothing is more important to us than ensuring that children's products are safe. We take our product safety responsibilities very seriously, and the measure of our success is the trust parents are able to place in our products, knowing that we're taking the right steps to protect children." (emphasis supplied).

**ANSWER:** The allegations contained in Paragraph 42 of the Complaint make no averments with respect to Medela and therefore no response is required by it. To the extent a response is required, Medela lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 42 of the Complaint.

43. On its website, Medela states, *inter alia*: "For over 25 years, it has been the commitment of Medela to provide the *highest quality breastfeeding and breast pumping products* available for mothers and professionals" (emphasis supplied).

**ANSWER:** Medela admits the allegations contained in Paragraph 43 of the Complaint.

- 44. Playtex provides this Q&A on its website:
  - Q7. What measures does Playtex maintain to regulate quality and safety?
  - A7. Our global manufacturing facilities are monitored by our Quality Assurance team and expert engineers. The Quality Assurance team includes experts with a minimum of 5 years of consumer product experience and a technical background.

Q10. Are the plastics and materials in Playtex® Infant feeding and soothing products safe for food contact application?

A10. All Playtex® Infant Care products contain materials that are safe for food contact application. We hold ourselves to a higher standard when it comes to infant safety. Playtex conducts tests of its products, and we only release products for sale that surpass the most stringent domestic and international regulatory guidelines on this and other safety matters. All materials are tested to ensure functional safety and performance and are tested or certified to meet material safety standards. Material testing is performed by a third party laboratory. (emphasis supplied).

**ANSWER:** The allegations contained in Paragraph 44 of the Complaint make no averments with respect to Medela and therefore no response is required by it. To the extent a response is required, Medela lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 44 of the Complaint.

However, despite their clear representations that the VPBPs were safe for 45. children, Defendants distributed VPBPs tainted with lead.

This Paragraph contains allegations directed to and pertaining to **ANSWER:** defendants other than Medela, and as to those allegations no response is required from Medela. To the extent a response to those allegations is required, Medela states that it lacks knowledge or information sufficient to form a belief as to the truth of the allegations pertaining to the other defendants. Medela denies the remaining allegations in Paragraph 45 of the Complaint. Further, Medela denies any allegation or implication that lead content of a product equates to actual exposure to lead, much less exposure to lead in concentrations that could be injurious. Medela further states that lead is hazardous only when an individual is actually exposed to lead, and exposed to sufficiently high levels of lead, and further that no individual was exposed to lead at any level based on reasonable use of Medela's bottle cooler carrier.

# F. The Class's Damages

46. The very children to which Defendants marketed their products as safe have now been exposed to poisonous lead that can cause serious long-term injury.

ANSWER: This Paragraph contains allegations directed to and pertaining to defendants other than Medela, and as to those allegations no response is required from Medela. To the extent a response to those allegations is required, Medela states that it lacks knowledge or information sufficient to form a belief as to the truth of the allegations pertaining to the other defendants. Medela denies the allegations in Paragraph 46 of the Complaint. Further, Medela denies any allegation or implication that lead content of a product equates to actual exposure to lead, much less exposure to lead in concentrations that could be injurious. Medela further states that lead is hazardous only when an individual is actually exposed to lead, and exposed to sufficiently high levels of lead, and further that no individual was exposed to lead at any level based on reasonable use of Medela's bottle cooler carrier.

47. Plaintiffs are not seeking some unspecified product from Defendants, but rather reimbursement for the cost of the defective and dangerous VPBPs. They are outraged that Defendants failed to determine that their baby products were contaminated by lead. Plaintiffs have no faith in the capacity of Defendants to provide a safe replacement product to their children and instead seek a full refund for the purchases made by them and the Class.

ANSWER: This Paragraph contains allegations directed to and pertaining to defendants other than Medela, and as to those allegations no response is required from Medela. To the extent a response to those allegations is required, Medela states that it lacks knowledge or information sufficient to form a belief as to the truth of the allegations pertaining to the other defendants. Medela admits that Plaintiff's Complaint includes a plea for "monies paid for" certain products. Medela denies the remaining allegations in Paragraph 47 of the Complaint. Further, Medela denies any allegation or implication that lead content of a product equates to actual exposure to lead, much less exposure to lead in concentrations that could be injurious.

Medela further states that lead is hazardous only when an individual is actually exposed to lead, and exposed to sufficiently high levels of lead, and further that no individual was exposed to lead at any level based on reasonable use of Medela's bottle cooler carrier.

48. Moreover, as a result of Defendants' negligent and reckless conduct, Plaintiffs' children and the Class have been significantly exposed to a known hazardous substance. As a result of such exposure, the children are at an increased risk of being poisoned by lead. Accordingly, Plaintiffs also seek to recover the costs of diagnostic testing necessary to detect lead poisoning to their children resulting from Defendants' actions.

ANSWER: This Paragraph contains allegations directed to and pertaining to defendants other than Medela, and as to those allegations no response is required from Medela. To the extent a response to those allegations is required, Medela states that it lacks knowledge or information sufficient to form a belief as to the truth of the allegations pertaining to the other defendants. Medela admits that Plaintiff's Complaint includes a plea for "damages in the amount of monies paid or to be paid for lead testing." Medela denies the remaining allegations in Paragraph 48 of the Complaint. Further, Medela denies any allegation or implication that lead content of a product equates to actual exposure to lead, much less exposure to lead in concentrations that could be injurious. Medela further states that lead is hazardous only when an individual is actually exposed to lead, and exposed to sufficiently high levels of lead, and further that no individual was exposed to lead at any level based on reasonable use of Medela's bottle cooler carrier.

### V. CLASS ACTION ALLEGATIONS

49. Plaintiff brings this action pursuant to Rules 23(a), 23(b)(1), 23(b)(2), and 23(b)(3) of the Federal Rules of Civil Procedure, on behalf of herself and a class ("Class") defined as:

All persons or entities who purchased (a) a vinyl cooler for storing breast milk made by Medela; (b) a carrying case for a First Years "Natural Transitions" breast pump made by RC2; or (c) a Playtex "Fridge to Go" vinyl baby bottle cooler.

Excluded from the Class are Defendants and any entities in which Defendants have a controlling interest; any entities in which Defendants' officers, directors, or employees are employed and any of Defendants' legal representatives, heirs, successors, or assigns; the Judge to whom this case is assigned and any member of the Judge's immediate family; and all persons or entities who properly execute and timely file timely requests for exclusion from the Class.

ANSWER: The allegations contained in Paragraph 49 of the Complaint state a legal conclusion, to which no response is required. To the extent a response is required, Medela lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 49 of the Complaint.

50. Plaintiff, on behalf of herself and the other members of the Class, seeks to recover damages and/or refunds from Defendants for consumer fraud under the Consumer Fraud laws of the 43 states and other state statutes for Defendants' false promises or concealment of material facts regarding the safety and composition of their VPBPs.

ANSWER: This Paragraph contains allegations directed to and pertaining to defendants other than Medela, and as to those allegations no response is required from Medela. To the extent a response to those allegations is required, Medela states that it lacks knowledge or information sufficient to form a belief as to the truth of the allegations pertaining to the other defendants. Medela denies the allegations in Paragraph 50 of the Complaint. Further, Medela denies any allegation or implication that lead content of a product equates to actual exposure to lead, much less exposure to lead in concentrations that could be injurious. Medela further states that lead is hazardous only when an individual is actually exposed to lead, and exposed to sufficiently high levels of lead, and further that no individual was exposed to lead at any level based on reasonable use of Medela's bottle cooler carrier.

51. This action satisfies the numerosity, commonality, typicality, adequacy, predominance, and superiority requirements of Rule 23 of the Federal Rules of Civil Procedure.

ANSWER: The allegations contained in Paragraph 51 of the Complaint state legal conclusions to which no response is required. To the extent a response is required, Medela denies the allegations in Paragraph 51 of the Complaint.

52. The requirement of Rule 23(a)(1) is satisfied here because the Class is so numerous that the individual joinder of all its members, in this or any action, is impracticable. The exact number or identification of Class members is presently unknown to Plaintiff, but it is believed that Class members number at least in the thousands. The identity of Class members is ascertainable. Class members may be informed of the pendency of this Class action by a combination of direct mail and public notice, or other means.

ANSWER: The allegations contained in Paragraph 52 of the Complaint state a legal conclusion to which no response is required. To the extent a response is required, Medela lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 52.

- 53. The "commonality" requirement of Rule 23(a)(2) is satisfied because there are questions of law or fact which are common to Plaintiff and each of the other members of the Class she seeks to represent. Those questions predominate over questions affecting only individual Class members. These questions include, but are not limited to:
  - a. Whether Defendants concealed, suppressed, or omitted any material fact with intent that consumers rely on such concealment, suppression, or omission in connection with the sale or advertisement of any merchandise;
  - b. Whether Plaintiff and the other members of the Class suffered any ascertainable loss of money or property as a result of Defendants' concealment, suppression, or omission of material fact;
  - c. Whether, as a result of Defendants' negligent and reckless conduct, children have been significantly exposed to a known hazardous substance;
  - d. Whether early detection, through medical testing of children, of lead poisoning is made necessary and advisable by the Defendants' manufacturing, marketing, and sale of the VPBPs;
  - e. Whether Defendants are refusing to pay for the costs of lead testing;

- f. Whether Plaintiff and Class members are entitled to injunctive relief; and
- g. Whether Plaintiff and other members of the Class are entitled to recover damages, including refunds, treble damages, interest, attorneys' fees, filing fees, and reasonable costs of suit for Defendants' injury to them.

ANSWER: The allegations contained in Paragraph 53 of the Complaint state legal conclusions to which no response is required. To the extent a response is required, Medela denies the allegations in Paragraph 53 of the Complaint.

54. Plaintiffs claims are typical of claims of the other Class members because they each arise from the same course of conduct by Defendants and are based on the same legal theories. Moreover, Plaintiff seeks the same forms of relief for herself as she does on behalf of absent Class members. Accordingly, Plaintiff has satisfied the "typicality" requirements of Rule 23(a)(3) with respect to the Class she seeks to represent.

ANSWER: The allegations contained in Paragraph 54 of the Complaint state legal conclusions to which no response is required. To the extent a response is required, Medela denies the allegations contained in Paragraph 54 of the Complaint.

55. Because her claims are typical of the claims of the other Class members she seeks to represent, Plaintiff has every incentive to vigorously pursue those claims. Plaintiff has no conflicts with, or interests antagonistic to, the other Class members. Plaintiffs commitment to the vigorous prosecution of this action is reflected in her retention of competent counsel experienced in litigation of this nature to represent her and the other Class members. Plaintiffs counsel will fairly and adequately represent the interests of the proposed Class and (a) have identified and thoroughly investigated the claims set forth herein; (b) are highly experienced in the management and litigation of class actions and complex litigation in general, including litigation of similar types of claims; (c) have extensive knowledge of the applicable law; and (d) possess the resources to commit to the vigorous prosecution of this action on behalf of the proposed Class. Accordingly, Plaintiff satisfies the adequacy of representation requirements of Rule 23(a)(4) with respect to the proposed Class.

ANSWER: The allegations contained in Paragraph 55 of the Complaint state legal conclusions to which no response is required. To the extent a response is required, Medela denies the allegations contained in Paragraph 55.

56. In addition, this action meets the requirements of Rule 23(b)(1). Absent a representative class action, members of the proposed Class would continue to suffer the harms described herein, for which they would have no remedy. Even if separate actions could be brought by individual Class members, the resulting multiplicity of lawsuits would cause undue hardship and expense for both the Court and the litigants, as well as create a risk of inconsistent rulings and adjudications that might be dispositive of the interests of similarly situated Class members, substantially impeding their ability to protect their interests, while establishing incompatible standards of conduct for Defendants.

ANSWER: The allegations contained in Paragraph 56 of the Complaint state legal conclusions to which no response is required. To the extent a response is required, Medela denies the allegations contained in Paragraph 56.

57. This action also meets the requirements of Rule 23(b)(2), in that Defendants have acted or refused to act on grounds generally applicable to Plaintiff and the other members of the Class, thereby making final injunctive or corresponding declaratory relief with respect to the Class appropriate.

ANSWER: The allegations contained in Paragraph 57 of the Complaint state legal conclusions to which no response is required. To the extent a response is required, Medela denies the allegations contained in Paragraph 57 of the Complaint.

58. This action additionally meets the requirements of Rule 23(b)(3). Common questions of law or fact, including those enumerated above, exist as to the claims of all members of the Class and predominate over questions affecting only individual Class members, and a class action is the superior method for the fair and efficient adjudication of this controversy. Class treatment will permit large numbers of similarly-situated persons to prosecute their respective class claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would produce. Furthermore, while damages to the Class are substantial in the aggregate, the damages to any individual Class member may be insufficient to justify individually controlling the prosecution of separate actions against Defendants.

ANSWER: The allegations contained in Paragraph 58 of the Complaint state a legal conclusion, to which no response is required. To the extent a response is required, Medela denies the allegations contained in Paragraph 58 of the Complaint.

59. This case is manageable as a class action, and a class trial will be manageable. Notice may be provided to Class members by First Class United States Mail and/or through the alternative means of publication and the Internet.

**ANSWER:** The allegations contained in Paragraph 59 of the Complaint state a legal conclusion, to which no response is required. To the extent a response is required, Medela denies the truth of the allegations contained in Paragraph 59 of the Complaint.

### VI. CLAIMS ALLEGED

# FIRST COUNT (Unfair and Deceptive Acts and Practices)

60. Plaintiff incorporates the allegations contained in each of the above paragraphs as if fully set forth herein.

<u>ANSWER:</u> Medela incorporates its responses to the allegations in the other paragraphs as if fully set forth herein.

61. The consumer protection and unfair and deceptive trade practices laws of 43 jurisdictions in the United States prohibit deceptive acts or practices in the conduct of any business trade or commerce or in the furnishing of any service and authorize a private right of action against defendants that violate those laws.<sup>1</sup>

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<sup>&</sup>lt;sup>1</sup> The state statutes Defendants are alleged to have violated are: Alaska (Alaska Stat. §§ 45.50.471 et seq.); Arizona (Ariz. Rev. Stat. § 44-1522); Arkansas (Ark. Code. §§ 4-88-107 and 4-88-108); California (Cal. Civ. Code § 1770(a)(19) and Cal. Bus. & Prof. Code §§ 17200 and 17500); Colorado (Colo. Rev. Stat. § 6-1-105(u)); Connecticut (Conn. Gen. Stat. § 42-110(b); Delaware (6 Del. Code § 2513); District of Columbia (D.C. Code § 28-3904(e),(f)); Florida (F.S.A. § 501.204); Hawaii (Haw. Rev. Stat. § 480-2(a)); **Idaho** (Idaho Code § 48-603(17),(18)); **Illinois** (815 Ill. Comp. Stat. 505/2); Indiana (Ind. Code § 24-5-0.5-3(a)); Kansas (Kan. Stat. §§ 50-626(a),(b) and 50-627(a)); Kentucky (Ky. Rev. Stat. § 367.170); Maine (Me. Rev. Stat. tit. 5, § 207); Maryland (Md. Code Corn. Law § 13-301(1),(3)); Massachusetts (Mass. Gen. Laws ch. 93A, §§ 2(a) and 9); Michigan (Mich. Stat. § 445.903(1)(s),(bb),(cc)); **Minnesota** (Minn. Stat. §§ 8.31 and 325F.67 and 325F.69(1)); **Missouri** (Mo. Rev. Stat. § 407.020); Nebraska (Neb. Rev. Stat. § 59-1602); Nevada (N.R.S. 598-0915(5),(15) and 598.0923(2)); New Hampshire (N.H. Rev. Stat. § 358-A:2); New Jersey (N.J.S.A. § 56:8-2); New Mexico (N.M.S.A. §§ 57-12-2(14),(17) and 57-12-3); New York (N.Y. Gen. Bus. Law § 349); North Carolina (N.C. Gen. Stat. §§ 75-1.1); North Dakota (N.D. Cent. Code §§ 51-15-02); Ohio (Ohio Rev. Code §§ 1345-02(A) and 1345-03(A) and 4165.02(7),(11) and §4165.03); Oklahoma (Okla. Stat. tit. 15, §§ 752 and 733 and tit. 78, § 53(9)); Oregon (Or. Rev. Stat. §§ 646.607(1) and 646.608(1)(i),(t),(u) and 646.608(2)); **Pennsylvania** (73 P.S. §201-2(1)(ix), 201-2(4)(xiv)); **Rhode Island** (R.I. Gen. Laws §§ 6-13.1-1(6)(ix),(xiii),(xiv) and 6-13.1-2); **South Dakota** (S.D. Codified Laws § 37-24-6(1)); **Tennessee** 

**ANSWER:** The allegations contained in Paragraph 61 of the Complaint state legal conclusions to which no response is required. To the extent a response is required, Medela states that the consumer protection and unfair and deceptive trade practices laws of 43 jurisdictions in the United States speak for themselves, and that Medela lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 61 of the Complaint.

As alleged above, Defendants' course of conduct is deceptive, because 62. Defendants failed to disclose that their VPBPs contained lead, which is likely to mislead or has the capacity to mislead consumers, including Plaintiff and the other members of the Class.

**ANSWER:** This Paragraph contains allegations directed to and pertaining to defendants other than Medela, and as to those allegations no response is required from Medela. To the extent a response to those allegations is required, Medela states that it lacks knowledge or information sufficient to form a belief as to the truth of the allegations pertaining to the other defendants. Medela denies the remaining allegations in Paragraph 63 of the Complaint. Further, Medela denies any allegation or implication that lead content of a product equates to actual exposure to lead, much less exposure to lead in concentrations that could be injurious. Medela further states that lead is hazardous only when an individual is actually exposed to lead, and exposed to sufficiently high levels of lead, and further that no individual was exposed to lead at any level based on reasonable use of Medela's bottle cooler carrier.

(Tenn. Code Ann. § 47-18-104(a)); **Texas** (Tex. Bus. & Corn. Code Ann. §§ 17.46(b)(9),(24) and 17.50); **Utah** (UCA 1953 §§ 13-11-4(1) and 13-11-5(1)); **Vermont** (Vt. Stat. Ann. tit. 9, § 2453(a)); **Washington** (RCWA §§ 19.86.020 and 19.86.920); West Virginia (W.Va. Code §§ 46A-6-102(b)(I),(L),(M) and 46A-6-104); Wisconsin (W.S.A. §§ 100.18 and 100.195 and 100.20 and 100.207); and Wyoming (WS § 40-12-105 (a)(x),(xv)).

63. As alleged above, Defendants omitted material facts about their VPBPs, with the intent that Plaintiff and the other members of the Class would rely on such omissions.

ANSWER: This Paragraph contains allegations directed to and pertaining to defendants other than Medela, and as to those allegations no response is required from Medela. To the extent a response to those allegations is required, Medela states that it lacks knowledge or information sufficient to form a belief as to the truth of the allegations pertaining to the other defendants. Medela denies the remaining allegations in Paragraph 63 of the Complaint. Further, Medela denies any allegation or implication that lead content of a product equates to actual exposure to lead, much less exposure to lead in concentrations that could be injurious. Medela further states that lead is hazardous only when an individual is actually exposed to lead, and exposed to sufficiently high levels of lead, and further that no individual was exposed to lead at any level based on reasonable use of Medela's bottle cooler carrier.

64. Defendants' conduct violates the consumer protection and unfair and deceptive acts and practices laws of each of the 43 jurisdictions at issue, and their deceptive acts and practices are continuing and will continue unless they are permanently enjoined. Plaintiff and members of the Consumer Protection Class have suffered injury as a direct and proximate result of Defendants' conduct, and Defendants are liable for compensatory and treble or other punitive damages, costs and attorneys' fees as each respective jurisdiction may permit, in amounts to be proved at trial.

ANSWER: This Paragraph contains allegations directed to and pertaining to defendants other than Medela, and as to those allegations no response is required from Medela. To the extent a response to those allegations is required, Medela states that it lacks knowledge or information sufficient to form a belief as to the truth of the allegations pertaining to the other defendants. Medela denies the remaining allegations in Paragraph 64 of the Complaint. Further, Medela denies any allegation or implication that lead content of a product equates to actual exposure to lead, much less exposure to lead in concentrations that could be injurious. Medela

further states that lead is hazardous only when an individual is actually exposed to lead, and exposed to sufficiently high levels of lead, and further that no individual was exposed to lead at any level based on reasonable use of Medela's bottle cooler carrier.

65. As alleged above, Defendants' course of conduct is also unfair: Defendants' conduct caused Plaintiff and the other members of the Class unjustified, substantial injuries which they could not avoid because of Defendants' material omissions; or such actions offend public policy, are immoral, unscrupulous, unethical, and offensive, and thereby cause substantial injury to consumers, including Plaintiff and the other members of the Class.

ANSWER: This Paragraph contains allegations directed to and pertaining to defendants other than Medela, and as to those allegations no response is required from Medela. To the extent a response to those allegations is required, Medela states that it lacks knowledge or information sufficient to form a belief as to the truth of the allegations pertaining to the other defendants. Medela denies the remaining allegations in Paragraph 65 of the Complaint. Further, Medela denies any allegation or implication that lead content of a product equates to actual exposure to lead, much less exposure to lead in concentrations that could be injurious. Medela further states that lead is hazardous only when an individual is actually exposed to lead, and exposed to sufficiently high levels of lead, and further that no individual was exposed to lead at any level based on reasonable use of Medela's bottle cooler carrier.

66. Plaintiff and the other members of the Class have each suffered injury in fact and monetary loss as a direct and proximate result of Defendants' conduct, including but not limited to, the monies paid to purchase their VPBPs. But for Defendants' course of conduct, including the misrepresentations and/or omissions alleged above, Plaintiff and the other members of the Class would have not purchased Defendants' VPBPs.

ANSWER: This Paragraph contains allegations directed to and pertaining to defendants other than Medela, and as to those allegations no response is required from Medela. To the extent a response to those allegations is required, Medela states that it lacks knowledge or

information sufficient to form a belief as to the truth of the allegations pertaining to the other defendants. Medela denies the remaining allegations in Paragraph 66 of the Complaint. Further, Medela denies any allegation or implication that lead content of a product equates to actual exposure to lead, much less exposure to lead in concentrations that could be injurious. Medela further states that lead is hazardous only when an individual is actually exposed to lead, and exposed to sufficiently high levels of lead, and further that no individual was exposed to lead at any level based on reasonable use of Medela's bottle cooler carrier.

67. Plaintiff and the other members of the Class are entitled to legal and equitable relief for Defendants' violation of each of the foregoing statutes, including, as applicable, damages, restitution, and/or disgorgement of all revenues, earnings, profits, compensation, and benefits which Defendants may have obtained from their above-described unlawful course of conduct, and an Order enjoining Defendants to cease and desist from engaging in those practices.

ANSWER: This Paragraph contains allegations directed to and pertaining to defendants other than Medela, and as to those allegations no response is required from Medela. To the extent a response to those allegations is required, Medela states that it lacks knowledge or information sufficient to form a belief as to the truth of the allegations pertaining to the other defendants. Medela denies the remaining allegations in Paragraph 67 of the Complaint. Further, Medela denies any allegation or implication that lead content of a product equates to actual exposure to lead, much less exposure to lead in concentrations that could be injurious. Medela further states that lead is hazardous only when an individual is actually exposed to lead, and exposed to sufficiently high levels of lead, and further that no individual was exposed to lead at any level based on reasonable use of Medela's bottle cooler carrier.

# SECOND COUNT (Breach of Implied Warranty)

Case 1:08-cv-02703

68. Count II is brought by Plaintiffs, individually, and on behalf of all similarly situated residents of Alaska, Arkansas, Colorado, Delaware, Hawaii, Louisiana, Maine, Maryland, Massachusetts, Mississippi, Montana, Nebraska, Nevada, New Hampshire, New Jersey, North Dakota, Oklahoma, South Carolina, South Dakota, Texas, Virginia, West Virginia and Wyoming (hereinafter "Implied Warranty Subclass"). Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth here.

ANSWER: Medela admits that Plaintiff asserts a second count in her Complaint, purporting to be brought on behalf of Plaintiff and all similarly situated residents of various states. Medela incorporates its responses to the allegations in the other paragraphs as if fully set forth herein.

69. At all times, there were in effect the following statutes governing the implied warranty of merchantability: Alaska Stat. § 45.02.314; Ark. Code Ann § 4-2 314; C.R.S. § 4-2¬314; 6 Del. C. § 2-314; H.R.S. § 490:2-314; § 554.2314; 11 M.R.S.A. § 2 314; Md. Code Ann. Art. 95B § 2-314; Mass. Gen. Laws Ch. 106 § 2-314; Miss. Code. Ann. § 75-2-314; M.C.A. 30- 2-314; Neb. U.C.C. 2-314; N.R.S. 104.2314; N.J.S.A. 12A:2-314; N.D.C.C. 2-314; O.S. 1991 § 2-314; R.I. Gen. Laws 1956 §6A-2-314; S.C. Code Ann. § 36-2-314; S.D.C.L. 57A-2-314; Tex. Bus. & Com. Code Ann. § 2-314; Va. Code § 8.2-314; W. Va. Code § 46-2-314; and Wyo. Stat. 34.1-2-314.

ANSWER: The allegations contained in Paragraph 69 of the Complaint state legal conclusions to which no response is required. To the extent a response is required, Medela states that the laws identified in Paragraph 69 speak for themselves, and that Medela lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 69 of the Complaint.

70. As designers, manufacturers, producers, marketers and sellers of toys, collectibles and juvenile and baby products, Defendants are "merchants" within the meaning of the various states' commercial codes governing the implied warranty of merchantability.

ANSWER: This Paragraph contains allegations directed to and pertaining to defendants other than Medela, and as to those allegations no response is required from Medela.

To the extent a response to those allegations is required, Medela states that it lacks knowledge or information sufficient to form a belief as to the truth of the allegations pertaining to the other defendants. The allegations contained in Paragraph 70 of the Complaint state legal conclusions to which no response is required. To the extent a response is required, Medela states that the states' commercial codes governing the implied warranty of merchantability speak for themselves, and Medela denies the allegations in Paragraph 70 of the Complaint.

71. The VPBPs are "goods," as defined in various states' commercial codes governing the implied warranty of merchantability.

ANSWER: This Paragraph contains allegations directed to and pertaining to defendants other than Medela, and as to those allegations no response is required from Medela. To the extent a response to those allegations is required, Medela states that it lacks knowledge or information sufficient to form a belief as to the truth of the allegations pertaining to the other defendants. The allegations contained in Paragraph 71 of the Complaint state legal conclusions to which no response is required. To the extent a response is required, Medela states that the states' commercial codes governing the implied warranty of merchantability speak for themselves, and that Medela lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 71 of the Complaint.

72. Implied in the sale of the VPBPs is a warranty of merchantability that requires, among other things, that the VPBPs pass without objection in the trade and are of merchantable quality and safe and fit for such use by young children.

ANSWER: The allegations contained in Paragraph 72 of the Complaint state legal conclusions to which no response is required. To the extent a response is required, Medela states that the states' commercial codes governing the implied warranty of merchantability speak for

themselves, and Medela denies the allegations in Paragraph 72 of the Complaint. Medela further states that its bottle cooler carrier is not intended for use by young children.

73. Because the VPBPs are defective and inherently dangerous, as a result of containing lead, the VPBPs are not able to function in their ordinary capacities and were therefore not merchantable at the times they were sold, as impliedly warranted by Defendants.

ANSWER: This Paragraph contains allegations directed to and pertaining to defendants other than Medela, and as to those allegations no response is required from Medela. To the extent a response to those allegations is required, Medela states that it lacks knowledge or information sufficient to form a belief as to the truth of the allegations pertaining to the other defendants. Medela denies the remaining allegations in Paragraph 73 of the Complaint.

74. Due to Defendants' wrongful conduct as alleged herein, Plaintiffs and members of the Class could not have known about the risks associated with the VPBPs.

ANSWER: This Paragraph contains allegations directed to and pertaining to defendants other than Medela, and as to those allegations no response is required from Medela. To the extent a response to those allegations is required, Medela states that it lacks knowledge or information sufficient to form a belief as to the truth of the allegations pertaining to the other defendants. Medela denies the remaining allegations in Paragraph 74 of the Complaint.

75. By virtue of the CEH's announcements and direct contact by the CEH, Defendants were put on notice of the defect in the VPBPs.

ANSWER: This Paragraph contains allegations directed to and pertaining to defendants other than Medela, and as to those allegations no response is required from Medela. To the extent a response to those allegations is required, Medela states that it lacks knowledge or information sufficient to form a belief as to the truth of the allegations pertaining to the other

defendants. Medela denies the remaining allegations in Paragraph 75 of the Complaint. Medela further states that CEH affirmatively decided not to pursue any of its allegations against Medela.

76. Defendants were also put on notice of the defect in the VPBPs by the numerous inquiries that they received concerning the defects.

ANSWER: This Paragraph contains allegations directed to and pertaining to defendants other than Medela, and as to those allegations no response is required from Medela. To the extent a response to those allegations is required, Medela states that it lacks knowledge or information sufficient to form a belief as to the truth of the allegations pertaining to the other defendants. Medela denies the remaining allegations in Paragraph 76 of the Complaint.

77. As a direct and proximate result of the Defendants' breach of implied warranty, Plaintiffs and members of the Class suffered damages as alleged herein.

ANSWER: This Paragraph contains allegations directed to and pertaining to defendants other than Medela, and as to those allegations no response is required from Medela. To the extent a response to those allegations is required, Medela states that it lacks knowledge or information sufficient to form a belief as to the truth of the allegations pertaining to the other defendants. Medela denies the remaining allegations in Paragraph 77 of the Complaint.

# THIRD COUNT (Negligence)

78. Count III is brought by all Plaintiffs, individually and on behalf of the Class. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth here.

ANSWER: Medela admits that Plaintiff asserts a third count in her Complaint, purportedly on behalf of Plaintiff and a putative class. Medela incorporates its responses to the allegations in the other paragraphs as if fully set forth herein.

79. Defendants had a duty to exercise reasonable care in the design, manufacture, sale, and/or distribution of the VPBPs into the stream of commerce, including a duty to assure that these products did not expose children to adverse health effects including, without limitation, IQ deficits, learning disabilities, behavioral problems, stunted growth or slowed growth, impaired hearing, kidney damage, mental retardation, and even death from lead poisoning.

ANSWER: This Paragraph contains allegations directed to and pertaining to defendants other than Medela, and as to those allegations no response is required from Medela. To the extent a response to those allegations is required, Medela states that it lacks knowledge or information sufficient to form a belief as to the truth of the allegations pertaining to the other defendants. As regards Medela, Medela states that the allegations contained in Paragraph 79 of the Complaint state legal conclusions to which no response is required. To the extent a response is required, Medela states that the laws of each state speak for themselves. Further, Medela denies that it breached or violated any duty it may have owed to Plaintiff or to the putative class members. Further, Medela denies any allegation or implication that lead content of a product equates to actual exposure to lead, much less exposure to lead in concentrations that could be injurious. Medela further states that lead is hazardous only when an individual is actually exposed to lead, and exposed to sufficiently high levels of lead, and further that no individual was exposed to lead at any level based on reasonable use of Medela's bottle cooler carrier. Medela denies the remaining allegations contained in Paragraph 79 of the Complaint.

80. Defendants failed to exercise ordinary care in the design, manufacture, sale, testing, quality assurance, quality control, and/or distribution of the VPBPs into interstate commerce in that Defendants knew or should have known that the VPBPs created a high risk of adverse health effects which can cause extraordinary suffering and even death. Defendants' failure to exercise reasonable care in the design, manufacture, sale, and/or distribution of the VPBPs was grossly negligent.

ANSWER: This Paragraph contains allegations directed to and pertaining to defendants other than Medela, and as to those allegations no response is required from Medela.

To the extent a response to those allegations is required, Medela states that it lacks knowledge or information sufficient to form a belief as to the truth of the allegations pertaining to the other defendants. Medela denies breaching or violating any duty it may have owed to Plaintiff or to the putative class members. Further, Medela denies any allegation or implication that lead content of a product equates to actual exposure to lead, much less exposure to lead in concentrations that could be injurious. Medela further states that lead is hazardous only when an individual is actually exposed to lead, and exposed to sufficiently high levels of lead, and further that no individual was exposed to lead at any level based on reasonable use of Medela's bottle cooler carrier. Medela denies the remaining allegations in Paragraph 80 of the Complaint.

- 81. Specifically, Defendants were grossly negligent in the design, manufacture, testing, advertising, warning, marketing, and/or sale of the VPBPs in that they:
  - Failed to use due care in designing and manufacturing the relevant products so as to avoid the aforementioned risks to children:
  - b. Failed to accompany their products with proper warnings regarding all possible adverse effects associated with young children's handling and mouthing of, and otherwise being exposed to, the relevant products;
  - Failed to conduct adequate testing and post-marketing surveillance to determine the safety of the relevant products;
  - Failed to warn Plaintiffs and members of the Class prior to actively encouraging the sale of the VPBPs either directly or indirectly, orally or in writing, about the following: (1) the possibility that young children handling or otherwise exposed to the VPBPs could suffer adverse health effects as described herein, and/or (2) the possibility of affected children requiring hospitalization and/or continuous medical monitoring as a result of exposure to the VPBPs; and
  - e. Were otherwise careless or grossly negligent.

This Paragraph contains allegations directed to and pertaining to ANSWER: defendants other than Medela, and as to those allegations no response is required from Medela. To the extent a response to those allegations is required, Medela states that it lacks knowledge or information sufficient to form a belief as to the truth of the allegations pertaining to the other defendants. Medela denies the remaining allegations in Paragraph 81 of the Complaint. Further, Medela denies any allegation or implication that lead content of a product equates to actual exposure to lead, much less exposure to lead in concentrations that could be injurious. Medela further states that lead is hazardous only when an individual is actually exposed to lead, and

exposed to sufficiently high levels of lead, and further that no individual was exposed to lead at

any level based on reasonable use of Medela's bottle cooler carrier.

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82. Despite the fact that Defendants knew or should have known that the VPBPs could cause unreasonable, adverse health effects to children, Defendants continued to market the relevant products to consumers including Plaintiff despite the possibility that these products could be produced without lead.

ANSWER: This Paragraph contains allegations directed to and pertaining to defendants other than Medela, and as to those allegations no response is required from Medela. To the extent a response to those allegations is required, Medela states that it lacks knowledge or information sufficient to form a belief as to the truth of the allegations pertaining to the other defendants. Medela denies the remaining allegations in Paragraph 82 of the Complaint. Further, Medela denies any allegation or implication that lead content of a product equates to actual exposure to lead, much less exposure to lead in concentrations that could be injurious. Medela further states that lead is hazardous only when an individual is actually exposed to lead, and exposed to sufficiently high levels of lead, and further that no individual was exposed to lead at any level based on reasonable use of Medela's bottle cooler carrier.

83. Defendants knew or should have known that consumers such as Plaintiffs and the Class would foreseeably suffer adverse health effects and injury as a result of Defendants' failure to exercise ordinary care as described above.

ANSWER: This Paragraph contains allegations directed to and pertaining to defendants other than Medela, and as to those allegations no response is required from Medela. To the extent a response to those allegations is required, Medela states that it lacks knowledge or information sufficient to form a belief as to the truth of the allegations pertaining to the other defendants. Medela denies the remaining allegations in Paragraph 83 of the Complaint. Further, Medela denies that it breached or violated any duty it may have owed to Plaintiff or to the putative class members. Further, Medela denies any allegation or implication that lead content of a product equates to actual exposure to lead, much less exposure to lead in concentrations that could be injurious. Medela further states that lead is hazardous only when an individual is actually exposed to lead, and exposed to sufficiently high levels of lead, and further that no individual was exposed to lead at any level based on reasonable use of Medela's bottle cooler carrier.

84. Defendants' negligence was a proximate cause of Plaintiffs' and the Class' economic damages, as well as their children's increased risk of harm as previously set forth herein.

ANSWER: This Paragraph contains allegations directed to and pertaining to defendants other than Medela, and as to those allegations no response is required from Medela. To the extent a response to those allegations is required, Medela states that it lacks knowledge or information sufficient to form a belief as to the truth of the allegations pertaining to the other defendants. Medela denies the remaining allegations in Paragraph 84 of the Complaint. Further, Medela denies any allegation or implication that lead content of a product equates to actual exposure to lead, much less exposure to lead in concentrations that could be injurious. Medela

further states that lead is hazardous only when an individual is actually exposed to lead, and exposed to sufficiently high levels of lead, and further that no individual was exposed to lead at any level based on reasonable use of Medela's bottle cooler carrier.

# FOURTH COUNT (Unjust Enrichment)

85. Plaintiff incorporates the allegations contained in each of the above paragraphs as if fully set forth herein.

ANSWER: Medela incorporates its responses to the allegations in the other paragraphs as if fully set forth herein.

86. Defendants have received a benefit from Plaintiff and the other members of the Class in the form of the monies Defendants received from Plaintiffs and other Class members' purchases of their VPBPs during the period of time relevant to this action.

ANSWER: This Paragraph contains allegations directed to and pertaining to defendants other than Medela, and as to those allegations no response is required from Medela. To the extent a response to those allegations is required, Medela states that it lacks knowledge or information sufficient to form a belief as to the truth of the allegations pertaining to the other defendants. As to Medela, the allegations contained in Paragraph 86 of the Complaint state legal conclusions to which no response is required. To the extent a response is required, Medela denies the allegations contained in Paragraph 86. Further, Medela denies any allegation or implication that lead content of a product equates to actual exposure to lead, much less exposure to lead in concentrations that could be injurious. Medela further states that lead is hazardous only when an individual is actually exposed to lead, and exposed to sufficiently high levels of lead, and further that no individual was exposed to lead at any level based on reasonable use of Medela's bottle cooler carrier.

87. Defendants have knowingly appreciated and accepted this benefit which has resulted and continues to result in an inequity to Plaintiff and the other members of the Class.

ANSWER: This Paragraph contains allegations directed to and pertaining to defendants other than Medela, and as to those allegations no response is required from Medela. To the extent a response to those allegations is required, Medela states that it lacks knowledge or information sufficient to form a belief as to the truth of the allegations pertaining to the other defendants. Medela denies the remaining allegations contained in Paragraph 87. Further, Medela denies any allegation or implication that lead content of a product equates to actual exposure to lead, much less exposure to lead in concentrations that could be injurious. Medela further states that lead is hazardous only when an individual is actually exposed to lead, and exposed to sufficiently high levels of lead, and further that no individual was exposed to lead at any level based on reasonable use of Medela's bottle cooler carrier.

88. Defendants' appreciation and acceptance of this benefit is inequitable.

ANSWER: This Paragraph contains allegations directed to and pertaining to defendants other than Medela, and as to those allegations no response is required from Medela. To the extent a response to those allegations is required, Medela states that it lacks knowledge or information sufficient to form a belief as to the truth of the allegations pertaining to the other defendants. Medela denies the remaining allegations contained in Paragraph 88. Further, Medela denies any allegation or implication that lead content of a product equates to actual exposure to lead, much less exposure to lead in concentrations that could be injurious. Medela further states that lead is hazardous only when an individual is actually exposed to lead, and exposed to sufficiently high levels of lead, and further that no individual was exposed to lead at any level based on reasonable use of Medela's bottle cooler carrier.

89. As a result of Defendants' unjust enrichment, Plaintiff and the other members of the Class sustained damages in an amount to be determined at trial. Plaintiff and the other members of the Class seek full disgorgement and restitution of Defendants' enrichment, benefits, and ill-gotten gains acquired as a result of the unlawful and/or wrongful conduct alleged herein.

ANSWER: This Paragraph contains allegations directed to and pertaining to defendants other than Medela, and as to those allegations no response is required from Medela. To the extent a response to those allegations is required, Medela states that it lacks knowledge or information sufficient to form a belief as to the truth of the allegations pertaining to the other defendants. Medela denies the remaining allegations contained in Paragraph 89. Further, Medela denies any allegation or implication that lead content of a product equates to actual exposure to lead, much less exposure to lead in concentrations that could be injurious. Medela further states that lead is hazardous only when an individual is actually exposed to lead, and exposed to sufficiently high levels of lead, and further that no individual was exposed to lead at any level based on reasonable use of Medela's bottle cooler carrier.

### **DEFENSES**

- 1. Failure to state a claim upon which relief can be granted.
- 2. Plaintiff's and the putative class members' claims are barred, in whole or in part, on the ground that they lack standing.
- 3. Plaintiff's and the putative class members' claims are barred, in whole or in part, because they have not been exposed to lead from Medela's bottle cooler carrier.
- 4. Plaintiff's and the putative class members' claims are barred, in whole or in part, by applicable Statutes of Limitations.
- 5. Plaintiff's and the putative class members' claims are barred, in whole or in part, because they did not rely on any alleged misrepresentation or omission.

6. Plaintiff's and the putative class members' claims are barred, in whole or in part, because any reliance by them was not reasonable.

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- 7. Plaintiff's and the putative class members' claims are barred, in whole or in part, because any alleged wrongdoing by Medela was not a proximate cause of any damage or injury allegedly suffered by Plaintiff and the putative class members.
- 8. Plaintiff's and the putative class members' claims are barred, in whole or in part, because any injuries attributable to exposure to lead are attributable to exposure to lead from sources other than Medela's bottle cooler carrier.
  - 9. Plaintiff's and the putative class members' claims are moot.
- 10. To the extent Plaintiff's and the putative class members' claims are based on a theory providing for liability without proof of causation, the claims violate Medela's rights under the U.S. Constitution.
- 11. Although Medela denies that Plaintiff and the putative class members are entitled to any relief, Plaintiff's and the putative class members' claims for equitable relief are barred, in whole or in part, by the availability of an adequate remedy at law and/or the lack of imminent harm.
- 12. Plaintiff's and the putative class members' claims for punitive or exemplary damages are contrary to the Due Process Clause of the Fourteenth Amendment of the U.S. Constitution, the Illinois Constitution, the Commerce Clause of the U.S. Constitution, and the equal protection and excessive fine provisions of the U.S. Constitution.
- 13. Medela hereby gives notice that it intends to rely upon any other defense that may become available or appear during the discovery proceedings in this case and hereby reserves its right to amend its Answer and Defenses to assert any such defenses.

14. Medela intends to rely upon, and reserves its right to assert, other and related defenses, as may become available in the event of a determination that this action, or some part

thereof, is governed by the substantive law of a state other than Illinois.

WHEREFORE, Medela Inc. respectfully requests that judgment be entered as follows: (1) that Plaintiff and the putative class members take nothing by way of the Complaint, with judgment entered in Medela's favor on all Counts of the Complaint; (2) that Medela recover its costs, disbursements, and attorneys' fees in this action; and (3) the Court award such other and further relief that it deems just and proper.

### **JURY DEMAND**

Medela hereby demands a trial by jury on all issues.

Dated: July 3, 2008

Respectfully submitted,

MEDELA INC.

By: /s/ Susan M. Benton
One of Its Attorneys

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#### **CERTIFICATE OF SERVICE**

I hereby certify that on this 3<sup>rd</sup> day of July 2008, I caused a copy of the foregoing document, DEFENDANT MEDELA INC.'S ANSWER AND DEFENSES TO PLAINTIFF JESSICA SMITH'S CLASS ACTION COMPLAINT, to be filed electronically. Notice of this filing will be sent to the attorneys listed below by operation of the Court's ECF system, which notice shall constitute service pursuant to Local Rule 5.9. Parties may access this filing through the Court's system.

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